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EVALUATION OF PRESCRIBING PATTERN OF DRUGS USED IN CIRRHOTIC PATIENTS WITH COMORBIDITIES AND COMPLICATIONS IN A TERITIARY CARE HOSPITAL

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ABSTRACT

Study objective: CLD is a major issue on a global scale and it affects people of all ages, genders, and ethnicities and is the root of a high number of medical consultations, hospital admissions, medical costs, morbidity and mortality. The aim is to study the prescribing pattern of drugs used in the treatment of CLD. The objectives are to assess the pattern of clinical features, risk factors, co-morbidities and complications associated with CLD. To assess the stages of cirrhosis and study the mortality rate of the patient using MELD score.

Methodology: A prospective observational study was conducted in a tertiary care hospital for a duration of 6 months.

Result: Among 68 participants, the majority of them were in the age group of 56- 65 (35.29%) and 53 (78%) of the study population were predominantly male. Diabetes (45.8%) was observed to be the major risk factor followed by alcohol (38.6%) and NASH (10.8%). The most observed clinical feature was abdominal distension (20/42%). Anemia (26%) and diabetes mellitus (22%) were the most commonly

observed comorbidities. Portal hypertension (30.32%) is the most common complication seen, followed by ascites and esophageal varices. The majority of participants belonged to Child-Pugh Class C and a MELD Na Score ranging 20-29 (50%). On evaluation, the most frequently prescribed drugs were gastrointestinal agents (38.49%) followed by dietary supplements (19.54%).

Conclusion: Chronic Liver Disease is increasingly becoming more prevalent, and part of this rise can be attributed to improved detection of risk factors, clinical features, complications and comorbidities. In-depth clinical care plans must include strategies for preventing, diagnosing, treating, and palliating these problems. Future interventions to raise public awareness of CLD should be taken promptly.

Keywords: Chronic Liver Disease (CLD); Liver cirrhosis; Risk factors; Model for end stage liver disease (MELD); Child- Pugh Classification

INTRODUCTION

Liver is one of the body's most vital organs. It aids in food digestion, detoxification of blood, and stores energy as carbohydrates for later use. The entire body will suffer if the liver cannot operate properly. Chronic liver injury causes damage to normal liver tissue resulting in the development of regenerative nodules surrounded by fibrous bands **[1]**. It is characterised by a steady decline in liver activities over a period of more than six months. CLD progresses through 4 stages namely Hepatitis (Inflammation), Fibrosis, Cirrhosis and Liver failure. Focus is given on the frequent aetiologies, clinical symptoms, and management of CLD because it is a clinical disorder that affects a lot of people.

Chronic Liver Disease has a wide range of aetiologies, including toxins, long-term alcohol consumption, infection, autoimmune diseases, genetic abnormalities, and metabolic problems. In India, HBV is the most prevalent cause of CLD, including cirrhosis and hepatocellular carcinoma. However, alcohol consumption is also rising rapidly. With a rising body mass index and diabetes prevalence, NASH burden is also increasing in India. In contrast, the prevalence of hepatitis C virus (HCV) is declining as a result of treatment initiatives.

The symptoms and signs appear gradually over several days or even years. The early symptoms are brought on by hepatic insufficiency, but as the disease progresses the symptoms are brought on by complications of the disease. Signs and symptoms of CLD include hepatomegaly, splenomegaly, pruritis, jaundice, palmar erythema, spider angiomata, gynecomastia, reduced libido, ascites, oedema, pleural effusion, respiratory difficulties, weight loss, encephalopathy and anaemia. Cirrhosis can lead to complications such as ascites, variceal bleeding, portal hypertension, hepatic encephalopathy, hepatocellular

carcinoma and coagulopathy. End-stage liver disease results in decreased quality of life, loss of social and economic productivity, and shortened survival.

CLD can be diagnosed through several ways like physical examination, laboratory investigations like full LFT, imaging studies like abdominal ultrasound with doppler, hepatic elastography, CT, MRI and hepatic biopsy. Once the diagnosis of liver cirrhosis is made, another important step is to score the disease. The main purpose of prognostic scores for patients with cirrhosis is to estimate the probability of death within a certain period. However, prognostic scores also represent a quantitative assessment of the "reserve" of liver function and the ability to withstand surgery or other aggressive therapeutic interventions.

Child-Pugh score is the traditional scale used by many physicians to evaluate liver disease severity. It uses laboratory tests (bilirubin, albumin, and prothrombin time) along with the presence and severity of encephalopathy and ascites to define three distinct classes of increasing severity of CLD (A, B and C). The Model for End-stage Liver Disease (MELD) is another scoring system which is widely used to prioritize people for liver transplantation. It uses three objective variables, bilirubin, creatinine and international normalized ratio (INR).

Medical treatments that may halt the progression of compensated cirrhosis to decompensated cirrhosis are currently being developed. [1] Management strategies for various complications of CLD include medications like beta adrenergic blockers, somatostatins, vasopressin, diuretics, endoscopic interventions like sclerotherapy and band ligation, surgical interventions like Transjugular Intrahepatic Portosystemic Shunt (TIPS), liver transplantation and various other methods. Current guidelines place EVL as a possible first option for primary prophylaxis in patients with high-risk medium to large varices **[2]**.

The major goals of managing patients with cirrhosis include delaying or halting the progression of liver disease, preventing further insults to the liver, identifying medications that require dose adjustments or should be avoided entirely, address symptoms and laboratory abnormalities, prevention, detection and treatment of complications of liver cirrhosis, determining the adequacy and optimal timing of liver transplantation.

METHODOLOGY

Study design

Prospective observational study was conducted in the Department of Gastroenterology at a tertiary care hospital consisting of 900 beds and offering a complete range of health care services.

Study population

All patients diagnosed with cirrhosis (above 35 age) admitted to Department of General

Medicine and Gastroenterology and those who satisfied the inclusion and exclusion criteria were selected for the study.

Sample size

The sample size was found to be 68 using the Cochran's formula:

$$\text{Sample size}, n = \frac{(Z\alpha_{/2})^2 \times pq}{d^2}$$

Where, N is the no. of samples, Z is the standardised normal interest, p is the proportion/ prevalence, q= 100-p, d is the absolute precision as 10% with confidence level (1-α) as 95%.

Inclusion criteria

The study included in-patients who were diagnosed with cirrhosis above the age of 35. Both male and female patients were included those who have given consent voluntarily to participate in the study.

Exclusion criteria

Subjects who are not willing to give consent and those admitted to departments other than General medicine and Gastroenterology were not included. Moreover, those who are below the age of 35 years, pregnant and lactating women, patients with underlying diseases like HIV and AIDS are also not included.

Brief procedure of the study

A Prospective Observational study was conducted in General Medicine and Gastroenterology Departments of a tertiary care teaching hospital. It was a 6-month study conducted after getting ethical committee's approval. A written informed consent form was obtained from the patient or care giver after giving a brief introduction about the study. Data collection form was used for recording the demographic details, past medical and medication history, reason for admission, clinical features, risk factors and complication. Information about current drug treatment [i.e., generic and trade name, formulation, dose, frequency, category of drugs] was collected and the collected data was further analysed based on aim and objectives.

Statistical analysis

The data collected was tabulated in an excel sheet and statistically analysed using SPSS Software version 20. The significance was determined using Chi-Square Test.

RESULT AND DISCUSSION

1. **Age wise distribution of patients with liver cirrhosis**

   Out of 68 cases of cirrhosis, 24 (35.29%) participants belonged to the age group of 56-65, followed by 19 (97.94%) in the age group of 66-75 and only 1 (1.47%) participant belonged to the age group ≥ 86 **(Figure 1)**.

2. **Gender wise distribution of patients with liver cirrhosis**

   Among 68 participants, 53 (77.94%) were males and 15 (22.06%) were females which was found similar to the study carried out by **Wasim M *et al* (2014) [3]**. In which majority of males,

17 (25%) belonged to the age group of 56-65 and only 1.47% to the age ≥ 86. Out of 15 females, 7 (10.29%) were belonged to age group of 56-65 and 66-75 each and remaining 1.47% belonged to the age group of 76-85 **(Figure 2)**.

3. **Distribution of participants based on social habit**

Out of 68 participants, 32 (47.06%) were alcoholic and 5 (7.35%) were smokers **(Figure 3)**.

4. **Distribution of participants based on clinical features**

Clinical features of cirrhosis vary from subject to subject. The most common clinical feature observed in our study population were abdominal distension (20.42%) abdominal pain (18.85%). Whereas abdominal pain was the most common clinical feature observed in the study carried out by **Vijayan M *et al.* (2014) [4]**, followed by generalized tiredness (11.52%), fever (10.47%), altered sensorium (6.81%), malena (5.24%), loss of appetite (4.71%), breathing difficulty (4.71%), hematemesis (4.71%), constipation (4.71%), vomiting (3.66%), diarrhoea (2.09%) and bleeding, dyspepsia and drowsiness each accounting for 1.05% **(Figure 4)**.

5. **Distribution of participants based on risk factors of cirrhosis**

The results of our study showed diabetes as a significant risk factor for cirrhosis accounting for 45.78% followed by alcohol 38.55%, NASH 10.84%, autoimmune hepatitis and hepatitis B each accounting for 2.41% **(Figure 5)**.

6. **Distribution of participants based on comorbidities**

Most common comorbidity observed was anemia (26.04%) followed by diabetes mellitus (22.49%), hypertension (18.93%), dyslipidemia (5.92%), respiratory problem (5.33%), CAD (4.73%), CKD (4.14%), AKI (4.14%), alcoholic hepatitis (3.55%) and hypothyroidism, stroke, cellulitis and HBV each accounting for 1.18%. Whereas the study, carried out by **Huma S *et al.* (2020) [5]** suggests hypertension as the most common comorbidity followed by diabetes mellitus **(Figure 6)**.

7. **Distribution of participants based on complications**

CLD progresses to decompensated cirrhosis which have increased risk of numerous complications and decreased life expectancy. From our study, the most common complications observed were portal hypertension (30.32%) and ascites (25.16%) which was similar to the study carried out by **Venkateshwarlu K *et al.* (2018) [6]**, followed by esophageal varices

(25.16%), hepatic encephalopathy (10.97%), SBP (4.52%), coagulopathy (2.58%) and hepatocellular carcinoma (1.29%) **(Figure 7)**.

8. **Distribution of participants based on Child-Pugh score**

   Decrease in liver function in patients may severely affect their ability to work and QOL. Therefore, it is necessary to determine the stage and prognosis of cirrhosis for the better management. Out of 68 participants, 45.59% belonged to Child-Pugh Class C followed by 44.12% Child B and 10.29% Child A, which was found similar to the study result carried out by **Baker IM *et al.* (2022) [7]**. The 1-year survival rate for Class A is 100%, Class B is 80% and that of Class C is 45% **(Figure 8)**.

9. **Distribution of participants based on Meld Na scoring**

   Out of 68 participants, 50% fell in MELD Na Score 20-29 and only 2.9% in <9 score, whereas **Rocha. H *et al.* (2018) [8]** carried out a study in which most of the participants fell in 10-19 MELD Na Score. The corresponding mortality rate for score 30-39 is 52.6%, 20-29 is 19.6%, 10-19 is 6% and < 9 is 1.9%. From this data we can interpret that only 10.3% of participants were at higher risk of mortality **(Figure 9)**.

10. **Prescribing trends of classes of drugs among cirrhotic patients**

    A total of 691 drugs were prescribed and evaluated, among them the most frequently prescribed class of drugs was GI agents (266) which was found similar to the result of study carried out by **Huma S *et al.* (2020) [5] (Figure 10)**.

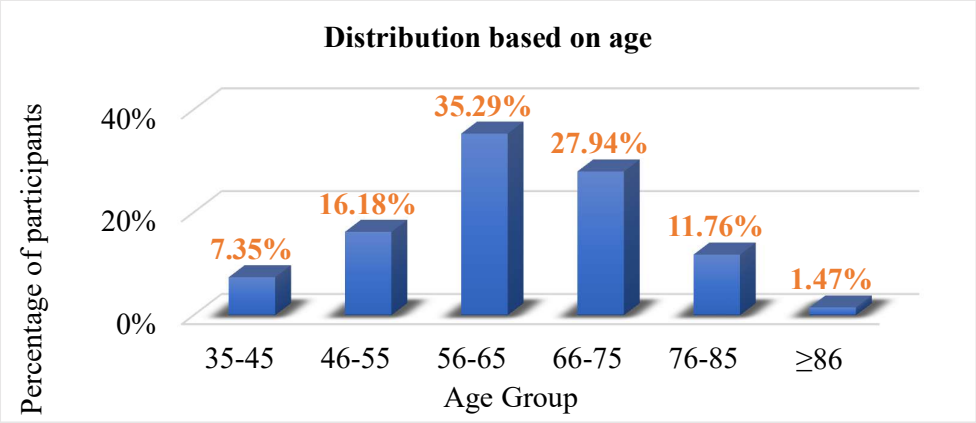

Figure 1: Distribution of Participants based on Age Group

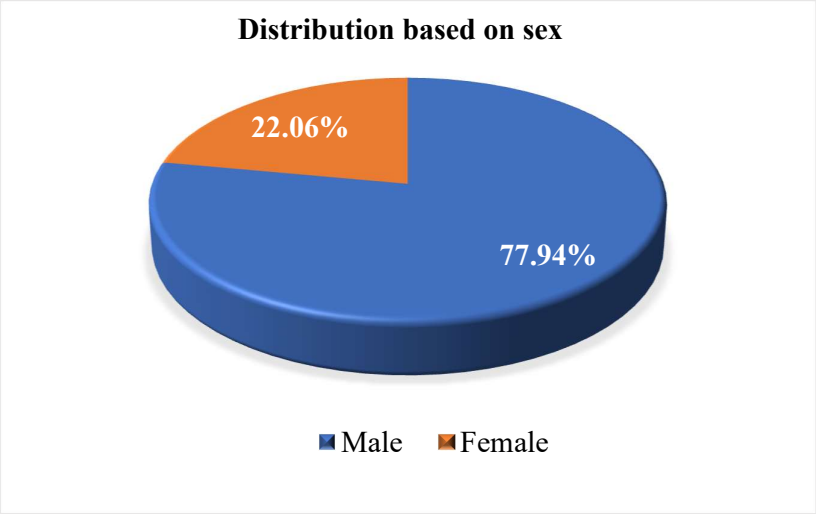

Figure 2: Distribution of Participants based on gender

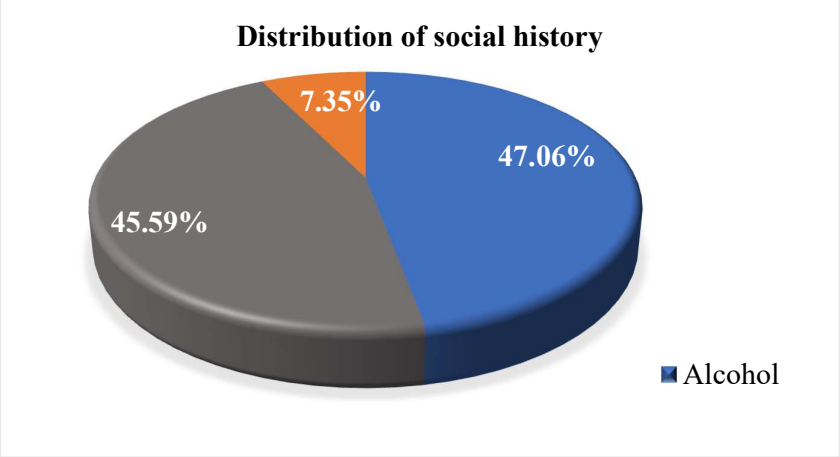

Figure 3: Distribution of participants based on social habit

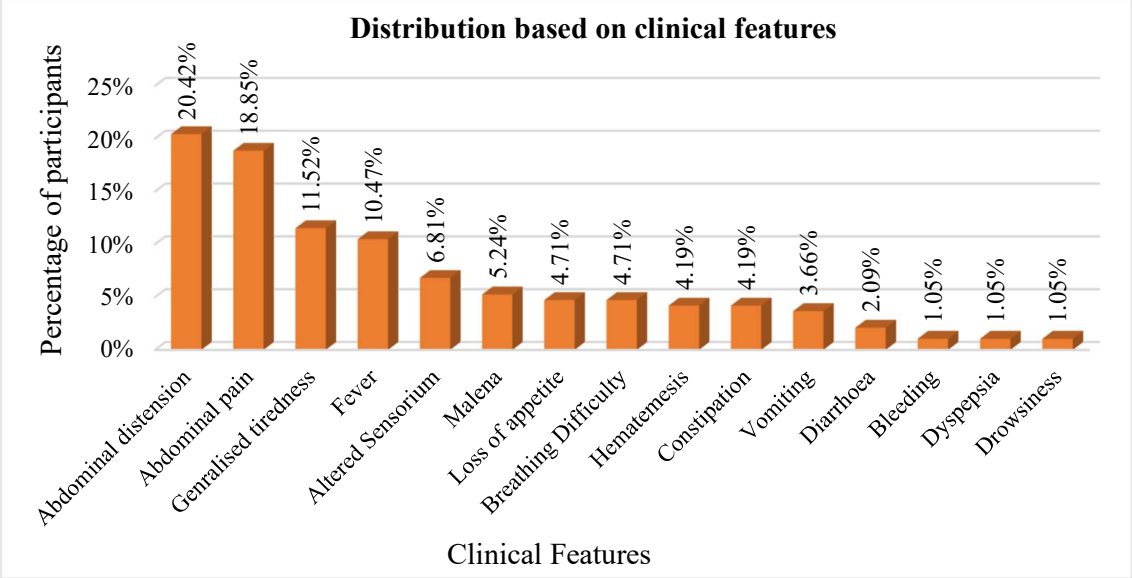

Figure 4: Distribution of Clinical features

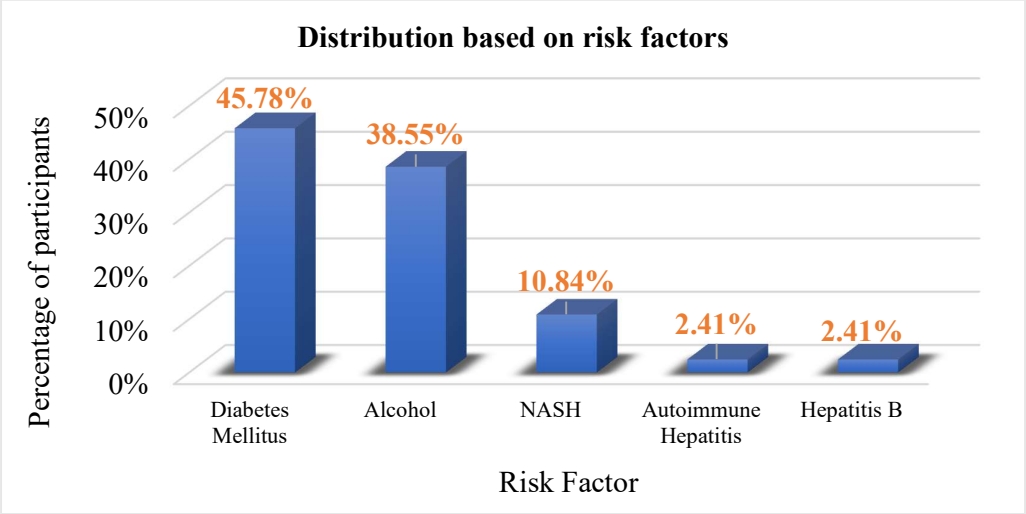

Figure 5: Distribution based on Risk factors

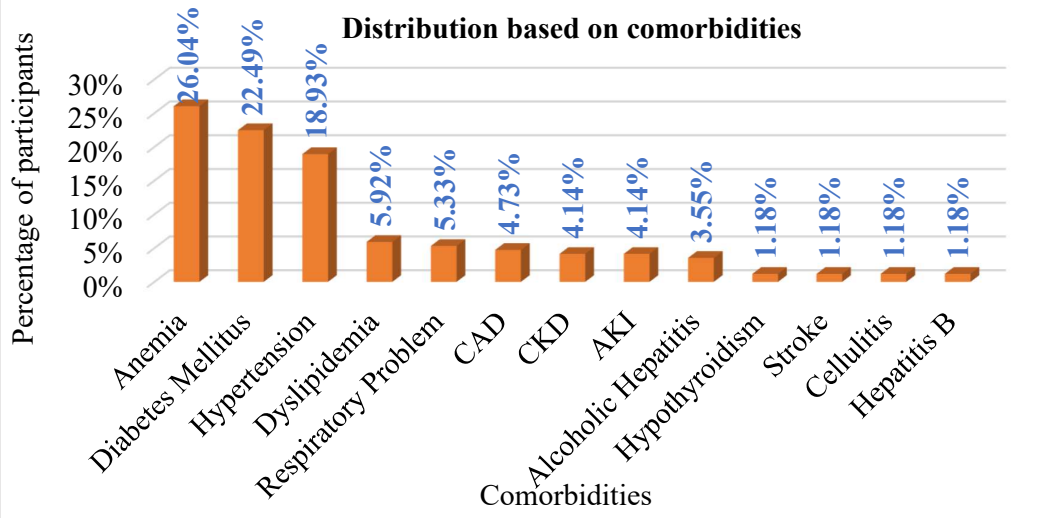

Figure 6: Distribution based on comorbidities

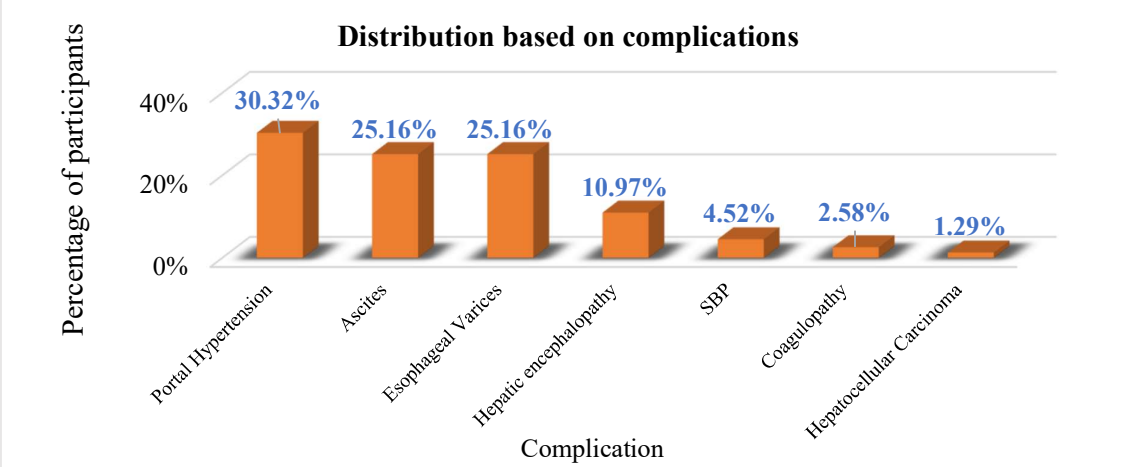

Figure 7: Distribution of participants based on complications

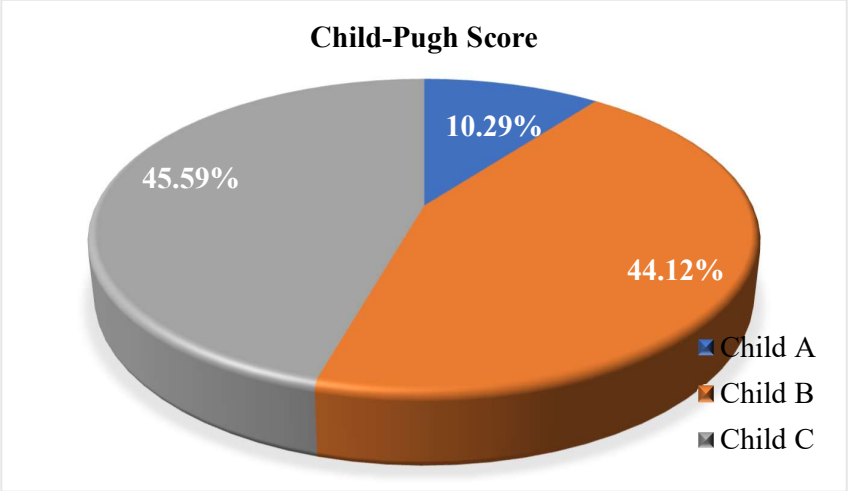

Figure 8: Distribution of category of cirrhosis as per Child-Pugh Classification

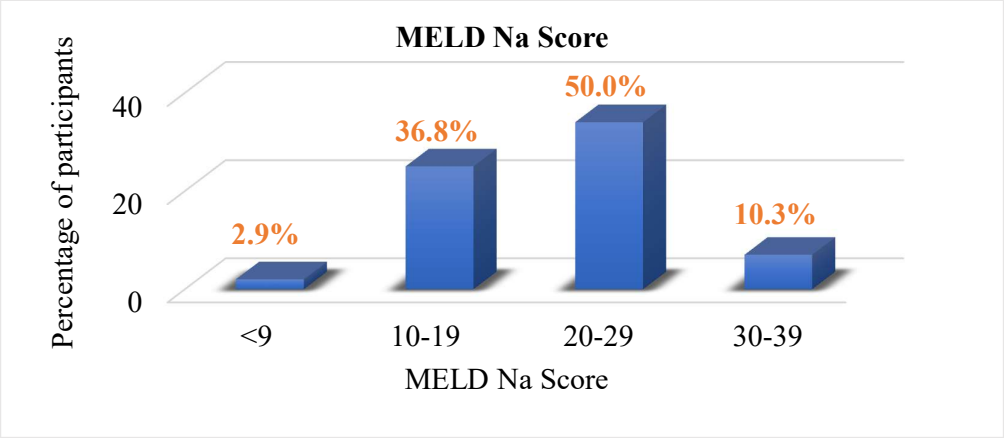

Figure 9: Distribution based on MELD Na Score

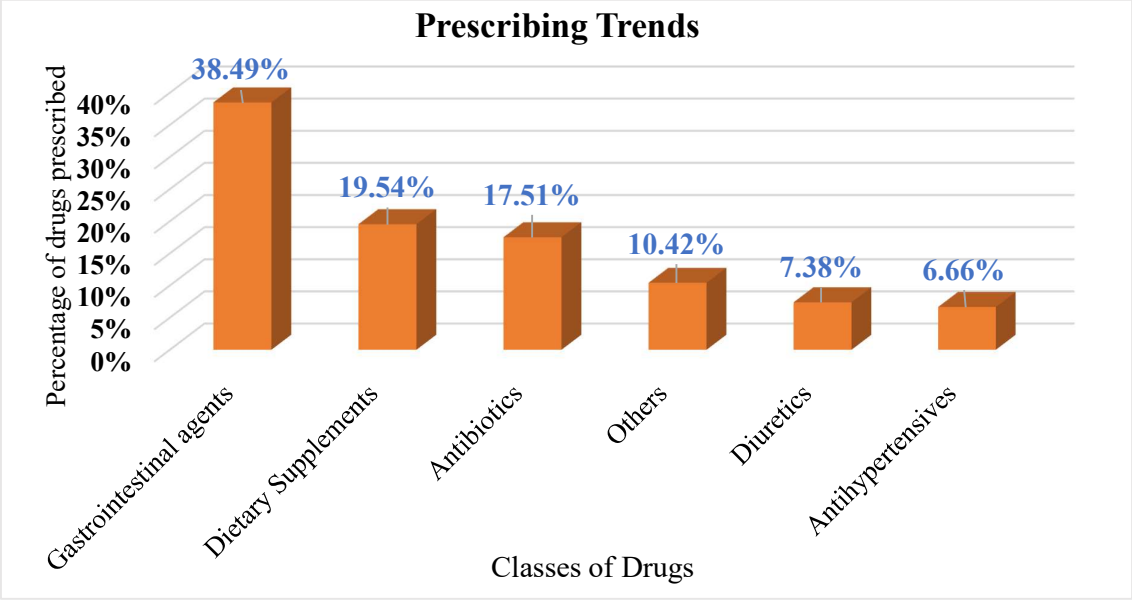

Figure 10: Drug use pattern among the study participants

CONCLUSION

Chronic Liver Disease is one of the major leading causes of mortality and morbidity in the Indian scenario. As it is more prevalent, the detection of risk factors, clinical features, complications and comorbidities along with the prescribing pattern of drugs are inevitable in the management of CLD. Patients with cirrhosis have progressive disease and suffer from multiple complications such as portal hypertension, variceal bleeding, ascites and hepatocellular carcinoma. In-depth clinical care plans must include strategies for preventing, diagnosing, treating, and palliating these problems. Future interventions to raise public awareness of CLD should be taken promptly.

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Conflict of interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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Ethical consideration

Institutional Ethics/Human Ethics Committee approval was obtained with IEC number: PCP/IEC-02B/12/PD-2022, PCP/IEC-02B/13/PD-2022, PCP/IEC-02B/14/PD-2022, PCP/IEC-02B/15/PD-2022.

REFERENCE

[1] Schuppan D and Afdhal NH. Liver cirrhosis. NIH Public Access. Lancet. 2008 March 8; 371(9615): 838–851.

[2] Garcia-Tsao G, Sanyal AJ, Grace ND, *et al.* Prevention and Management of Gastroesophageal Varices and Variceal Haemorrhage in Cirrhosis. AASLD Practice Guidelines. 2007 August 24; 46(3): 922-938.

[3] Wasim M, Biland B, Idrees M, *et al.* Assessment of Risk Factors and Clinical Presentations in a Liver Cirrhotic State-Pakistan. World Applied Sciences Journal. 2014 December 25; 32(7): 1252-1257.

[4] Vijayan M, Anisha K A, Selina SK and Roshni P R. Clinical Profile and Prescribing Pattern of Cirrhosis in a Tertiary Care Hospital. Indian Journal of

Pharmacy Practice, 2014 July–September; 7(3): 69-74.

[5] Huma S, Fatima ON, Ayesha I, *et al.* Prescribing Pattern of Drugs Used in Chronic Liver Disease with Co Morbid Conditions and Assessment of Severity using MELD Score: A Prospective Observational Study. JDDT [Internet]. 2020 October 15; 10(5-s):19-24.

[6] Venkateshwarlu K, Kowshik K, Anusha K, Sourab S, Rushi AR. A Study on Management of Comorbidity and Complications in Liver Cirrhosis Patients. IOSR Journal of Pharmacy. 2018 April 7; 8(4): 54-59.

[7] Baker I M, Rahman M M, Talukder S, *et al.* Child-Pugh Score of Decompensated Chronic Liver Disease Patient as a Predictor of Short-Term Prognosis. SAS J Med. 2022 February; 8(2): 58-66.

[8] Rocha H, Puentes JCP, Nicolau S, Ferrao G. Effectiveness of the MELD/Na Score and the Child-Pugh Score for the Identification of Palliative Care Needs in Patients with Cirrhosis of the Liver. Indian J Palliat Care. 2018 October-December; 24(4): 526-528.

[9] Banait S, Badole SM, Jain J, Thorat A. Risk factors for Chronic Liver Disease in population of Central India: a case-control study from rural India. Egyptian Liver Journal. 2021 December; 11(1): 1-9.

[10] Al-Khazraji KA, Hashim MK, Abdulla4 MK, *et al.* Etiologies of Liver Cirrhosis and Their Clinical Presentation among Inpatients in Medical City Complex- Baghdad Teaching Hospital. Global Journal of Health Science. 2021 April 13; 13(5): 64-80.